K091545

Section 10: Summary

510(k) Summary

JUN 15 2009

Prepared: April 22, 2009

Submitter:

Company Name:	Canon USA, Inc. (U.S. agent for Canon Inc.)
Company Address:	One Canon Plaza
	Lake Success, NY 11042
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Proposed Device:

Reason For 510(k):	New Model
Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-60C
Classification Name:	MQB, Solid State X-ray Imager
FDA 510(k) #:	To be assigned

Predicate Device:

Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-60G
Classification Name:	MQB, Solid State X-ray Imager
FDA 510(k) #:	K081648

Predicate Device:

Manufacturer:	Canon Inc.
Trade Name:	Canon
Model Name:	CXDI-50C
Classification Name:	MQB, Solid State X-ray Imager
FDA 510(k) #:	K060433

Description of Device:

The DIGITAL RADIOGRAPHY CXDI-60C is a solid state x-ray imager which has 23x28cm imaging area.

The DIGITAL RADIOGRAPHY CXDI-60C intercepts x-ray photons and the scintillator of the CXDI-60C emits visible spectrum photons that illuminate an array of photo-detectors that create an electrical signals.

After the electrical signals are generated, it is converted to digital value, and the images will be displayed on monitors.

Intended Use: DIGITAL RADIOGRAPHY CXDI-60C provides digital image capture for conventional film/screen radiographic examinations.

The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.

This device is not intended for mammography applications.

Comparison to Predicate: CXDI-60C's intended use is the same as that of CXDI-60G and CXDI-50C.

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However, the differences in the material for fluorescent screen of CXDI-60G are as follows:

Both the CXDI-60C and the CXDI-60G use the same amorphous silicon alley as the sensing means, however, the CXDI-60C uses the different material for fluorescent screen which is deposited on the amorphous silicon array with from the CXDI-60G. The CXDI-60C uses CsI (Cesium Iodide) while CXDI-60G uses GOS (Gadolium Oxy-Sulfide). Because of CsI which provides high x-ray absorption as fluorescent screen, CXDI-60C delivers diagnostic images with the x-ray dosage less than that required by CXDI-60G and CXDI-60C's DQE approximately doubles compared to CXDI-60G.

Also, the differences in the external dimensions and the weight of CXDI-50C are as follows:

- The external dimensions of CXDI-50C is changed from 491x477x23mm to 344x380x22.5mm.
- The weight of CXDI-55G is changed from 4.8Kg to 2.5Kg.

Conclusion: The Performance Data demonstrate that CXDI-60C is as safe and effective as CXDI-60G. Based on the information in this submission, similarity to the predicate device (Digital Radiography CXDI-60G and CXDI-50C), and the results of our design control activities and non-clinical testing, it is the opinion of Canon Inc. that the DIGITAL RADIOGRAPHY CXDI-60C described in this submission is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Canon USA, Inc.
% Mr. Jeff D. Rongero
Third Party Reviewer-Senior Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709

AUG 23 2013

Re: K091545
Trade/Device Name: CXDI-60C
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: May 26, 2009
Received: May 27, 2009

Dear Mr. Rongero:

This letter corrects our substantially equivalent letter of June 15, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications Statement

510(K)Number(if known): K091545

Device Name: CXDI-60C

Indications for Use:

DIGITAL RADIOGRAPHY CXDI-60C provides digital image capture for conventional film/screen radiographic examinations.
The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures.
This device is not intended for mammography applications.

Prescription Use ___X___ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHERT PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091545